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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,793	05/24/2001	Gregory Murphy	28122.90	2880

35690 7590 06/20/2005

MEYERTONS, HOOD, KIVLIN, KOWERT & GOETZEL, P.C.
P.O. BOX 398
AUSTIN, TX 78767-0398

EXAMINER	
MATTHEWS, WILLIAM H	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/864,793	MURPHY ET AL.	
	Examiner	Art Unit	
	William H. Matthews (Howie)	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-19,25,27-38,40-50,52-62 and 64-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-19,25,27-38,40-50,52-62 and 64-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2-7-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 15-19,25,27-38,40-50,52-62, and 64-86 have been considered but are not persuasive.

2. With regard to section D of Applicant's remarks section, Applicant appears to contend Martin lacks "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns". Examiner disagrees because Martin discloses fibers attached to a sheet providing for a distinct pattern of concentric circles capable of Applicant's intended use.

3. With regard to section E of Applicant's remarks section, Applicant contends Alt's electrical leads attached to the patch may inhibit Alt's invention from functioning as a patch. Applicant has not provided a particular reason to support this position and the Examiner does not understand how leads extending from the side or outer surface of the electrode patch inhibit use of the device. With regard to claims 15,17, and 19 Applicant argues intended use recitations which do not provide particular structural limitations to the device. With regard to claims 29,42, and 66 Applicant argues Alt lacks "markings imprinted on the material with radiopaque ink". This limitation provides a Product by Process limitation explained in MPEP 2113 which states "Product by Process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.". Examiner refers to column 16, lines 11-27 described doping or coating the fibers with radiopaque materials to provide viewing under

fluoroscopy and results in the structure implied by ""markings imprinted on the material with radiopaque ink".

4. With regard to section F of Applicant's remarks section, Applicant contends Milijasevic's device can not fulfill the functions of Applicant's invention (sealing patch) because of the slits and porous envelope. Examiner directs Applicant to columns 5-6 describing the dacron envelope as porous on the heart facing wall to promote fixation by tissue ingrowth, and that the opposite wall need not be porous. Furthermore, Applicant's claims lack limitations requiring the patch to be non-porous or porous.

5. With regard to section G of Applicant's remarks section, Applicant contends Baker's electrical leads attached to the patch may inhibit Baker's invention from functioning as a patch. Applicant has not provided a particular reason to support this position and the Examiner does not understand how leads extending from the side or outer surface of the electrode patch inhibit use of the device.

6. With regard to section H of Applicant's remarks section, Applicant contends King lacks "reshaping the enlarged ventricle to an appropriate size and shape of a normal left ventricle to create a reshaped ventricle; and closing the opening in the reshaped ventricle with an active patch.". This limitation is found no where in Applicant's claims so King need not teach this feature to anticipate the claims. Applicant also contends the rigid struts of King's device inhibit post-operatively evaluating movement of the patch. Examiner disagrees because the radiopaque struts of King would allow a physician to see if the patch moved into a different position.

7. With regard to section I of Applicant's remarks section, Applicant contends there is no motivation to modify the spacing of the electrical leads in Alt to 1 cm. Examiner maintains his position that Applicant has not disclosed an advantage, a particular purpose, or solving a stated problem by using the specific 1 cm spacing and furthermore that the spacing disclosed by Alt would perform equally as 1 cm spacing because both provide sufficient visibility under fluoroscopy.

8. With regard to section J of Applicant's remarks section, Applicant contends there is no motivation to use platinum threads or ion deposition. Examiner disagrees because the motivation is to provide sufficient visibility under fluoroscopy to enable a physician to view placement and movement of the patch.

9. With regard to section K of Applicant's remarks section, Applicant contends there is no motivation to combine the teachings of Alt and Milijasevic by wrapping Alt's defribillator in a polyester mesh. Examiner disagrees because Alt discloses an insulating layer 7 (lines 5-16 of col. 13) but lacks express disclosure of the insulating layer comprising polyester. Milijasevic teaches in lines 46 of col. 5 through line 24 of col. 6 a patch comprising an insulating layer of polyester to prevent burning of tissue. Examiner uses Milijasevic to teach obviousness of using polyester as taught by Milijasevic for the insulating layer of Alt.

10. With regard to sections L-N of Applicant's remarks section, Applicant contends the references fail to teach "wherein the biocompatible material is formed of threads produced by co-extruding the material with radiopaque polymeric material" or "wherein the biocompatible material is formed of threads made from a mixture of polymeric

material and barium sulfate". Regarding the first limitation, Applicant is directed to MPEP 2113 which recites "Product by Process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.". Therefore the claim implies a structure having a biocompatible material and radiopaque polymeric material. Zhong is used in each rejection to teach it is known in the art of ventricular patches to provide a biocompatible material mixed with barium sulfate to provide visibility under fluoroscopy.

11. With regard to sections O and P of Applicant's remarks section, Applicant contends there is no motivation to combine Buckberg with any of Alt, Baker, Milijasevic, or Martin to teach biocompatible material being collagen impregnated, comprising bovine pericardium, or comprising porcine tissue. Examiner disagrees because Buckberg teaches ventricular patches using biocompatible material being collagen impregnated, comprising bovine pericardium, or comprising porcine tissue as an alternative to commonly used Dacron or PTFE material in order to provide improved biocompatibility after implantation.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 18,52,53-55,62,83 are rejected under 35 U.S.C. 102(e) as being anticipated by Martin et al. US PN 6,162,537.

Martin et al. discloses a ventricular patch (lines 34-47 of col. 12) having a combination of fibers that are treated with radiopaque dyes before or after extrusion (see line 61 of col. 7 through line 58 of col. 8, lines 7-13 of col. 9, and line 59 of col. 9 through line 15 of col. 10). The second fiber may be polyester (lines 12-31 of col. 7) and the first component may be collagen (lines 25-41 of col. 6).

3. Claims 15,17,19,25,28,29,32,34-36,38,41,42,45,47-49,65,66,69, and 71-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt US PN 5,411,527.

Alt discloses a ventricular patch in figure 2 comprising metal thread markings or ink markings on a biocompatible surface in either a grid, parallel lines, or lines radiating from a point. See lines 42-52 of col. 10, lines 4-22 of col. 11, line 61 of col. 11 through line 2 of col. 12, lines 5-16 of col. 13, and lines 11-27 of col. 16.

4. Claims 18,19,53,57-61,65,69-74,83, and 86 are rejected under 35 U.S.C. 102(b) as anticipated by Milijasevic US PN 4,938,231.

Milijasevic discloses a ventricular patch in figures 2 and 10 having radiopaque threads (platinum or stainless steel threads) enveloped by a polyester mesh. (see lines

34-62 of col. 3 and line 45 of col. 5 through line 25 of col. 6). Radiating line patterns (figure 10) or concentric circle patterns (figure 11) are disclosed.

5. Claims 15,17,19,28,32,34,38,41,45,47,65,69,71 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker, Jr. et al. US PN 4,821,723.

Baker Jr. et al. discloses in figures 1a-1b and lines 39-61 of col. 6 a ventricular patch comprising a plurality of radiopaque markings coupled to a sheet and arranged in a pattern of lines radiating from a single point, equally spaced parallel lines, or uniform grid of horizontal and vertical lines.

6. Claims 19,64,65,86 are rejected under 35 U.S.C. 102(b) as being anticipated by King et al. US PN 3,874,388.

King et al. discloses in figure 1c and lines 14-55 of col. 6 a ventricular patch comprising a plurality of radiopaque markings coupled to a sheet and arranged in a pattern of lines radiating from a single point. The sheet material may include pericardium which inherently contains collagen.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alt US PN 5,411,527.

Alt discloses the use of metal threads in figure 2 and lines 34-40 of col. 11, but Alt does not disclose expressly the use of spacing set at 1cm.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use 1cm spacing because Applicant has not disclosed that using 1cm spacing provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the spacing used by Alt because both would provide sufficient visibility under fluoroscopy during implantation of the patch.

Therefore, it would have been an obvious matter of design choice to modify Alt to obtain the invention as specified in claim 16.

9. Claims 33,37,46,50,70, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt US PN 5,411,527.

Alt meets the structural limitations of claims 33,37,46,50,70, and 74 as described above, but lacks the express disclosure of using platinum threads or using ion deposition to deposit radiopaque substances to the markings. However, Alt discloses in lines 42-52 of col. 10 and lines 11-27 of col. 16 that platinum-iridium wires or other metals may be used, and that polymer threads may be used that are coated with

radiopaque materials. Furthermore, the particular use of ion deposition or platinum is widely known in the art of medical devices in order to provide sufficient visibility under fluoroscopy during implantation.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have selected platinum as the material for the wire or to use ion deposition as a method of coating the polymer wires in order to provide sufficient visibility under fluoroscopy during implantation.

10. Claims 77,80,86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt US PN 5,411,527 as applied in the 102(b) rejection above, and in further view of Milijasevic US PN 4,938,231.

Alt meets the structural limitations of claims 26,39, and 63 as described above, but lacks the express disclosure of the biocompatible material comprising polyester. Milijasevic teaches a ventricular patch enveloped by a polyester mesh in order to prevent burning of tissue during delivery of current. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the patch disclosed by Alt by using a polyester mesh, as taught by Milijasevic, for the biocompatible material in order to prevent burning of tissue during delivery of current.

11. Claims 30,31,43,44,67,68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. US PN 4,821,723 as applied in the 102(b) rejection above and in further view of Zhong et al. US PN 6,368,356.

Baker, Jr. et al. meets the structural limitations of claims 30,31,43,44,67,68 as described above, but lacks the express disclosure of a polymer made with barium sulfate. Zhong et al. teaches a ventricular patch wherein the polymer base is embedded with barium sulfate filler material in order to provide sufficient visibility under fluoroscopy during implantation.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the patch disclosed by Baker, Jr. et al. by using a polymer made with barium sulfate in order to provide sufficient visibility under fluoroscopy during implantation as taught by Zhong et al.

Note MPEP 2113 (Product by Process) for claims 55 and 67. The claims are not limited by the manipulations of the recited steps, only the structure implied by the steps.

12. Claims 55,56,67, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milijasevic US PN 4,938,231 as applied in the 102(b) rejection above and in further view of Zhong et al. US PN 6,368,356.

Milijasevic meets the structural limitations of claims 55,56,67, and 68 as described above, but lacks the express disclosure of a polymer made with barium sulfate. Zhong et al. teaches a ventricular patch wherein the polymer base is embedded with barium sulfate filler material in order to provide sufficient visibility under fluoroscopy during implantation.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the patch disclosed by Milijasevic by using a polymer made with barium sulfate in order to provide sufficient visibility under fluoroscopy during implantation as taught by Zhong et al.

Note MPEP 2113 (Product by Process) for claims 55 and 67. The claims are not limited by the manipulations of the recited steps, only the structure implied by the steps.

13. Claim 56 rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al. US PN 6,162,537 as applied above in the 102(e) rejection, and in further view of Zhong et al. US PN 6,368,356.

Martin et al. meets the structural limitations of claim 56 as described above by disclosing a polymer material made with a radiopaque dye or pigment, but lacks the express disclosure of a polymer made with barium sulfate. Zhong et al. teaches a ventricular patch wherein the polymer base is embedded with barium sulfate filler material in order to provide sufficient visibility under fluoroscopy during implantation.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the patch disclosed by Martin et al. by using a polymer made with barium sulfate in order to provide sufficient visibility under fluoroscopy during implantation as taught by Zhong et al.

14. Claims 27,40,64,75,76,78,79,84, and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt US PN 5,411,527 or Baker Jr. et al. US PN 4,821,723 as applied above, and in further view of Buckberg et al. US PN 6,450,171.

Alt or Baker, Jr. et al. meet the structural limitations of claims 27,40,64,75,76,78,79,84, and 85 as described above, but lacks the express disclosure of using a sheet made with collagen, porcine tissue or bovine pericardiuim. Buckberg et al. teaches a ventricular patch wherein the sheet is made of collagen, porcine tissue or bovine pericardiuim in order to provide improved biocompatibility upon implantation.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the patch disclosed by Alt or Buckberg et al. by using a sheet made with collagen, porcine tissue or bovine pericardiuim in order to provide improved biocompatibility upon implantation as taught by Buckberg et al.

15. Claims 52,81,82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milijasevic US PN 4,938,231or Martin et al. US PN 6,162,537 as applied above, and in further view of Buckberg et al. US PN 6,450,171.

Milijasevic or Martin et al. meet the structural limitations of claims 52,81,82 as described above, but lacks the express disclosure of using a sheet made with collagen, porcine tissue or bovine pericardiuim. Buckberg et al. teaches a ventricular patch wherein the sheet is made of collagen, porcine tissue or bovine pericardiuim in order to provide improved biocompatibility upon implantation.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the patch disclosed by Milijasevic or Martin et al. by using a sheet made with collagen, porcine tissue or bovine pericardiuim in order to provide improved biocompatibility upon implantation as taught by Buckberg et al.

Conclusion

16. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

WHM
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CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700